Title: Safety and Efficacy of 2% Bisulfite-Free Chloroprocaine with and without Epinephrine for Epidural Anesthesia in the Parturient

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Introduction: Chloroprocaine has been a popular local anesthetic in obstetrics for many years since it has a potent and rapid local anesthetic action with low maternal and fetal cardiovascular toxicity. Recently a number of reports described rare occasions where intended epidural blocks with 2-chloroprocaine may have resulted in spinal anesthesia with irreversible neurotoxicity (1). Several experimental investigations have led to the hypothesis that the permanent or prolonged paralysis may be due to the low pH and the bisulfite concentrations of 0.2% (2). The purpose of the present study is to evaluate the efficacy and the safety of a reformulation of 2% bisulfite-free chloroprocaine with and without epinephrine for epidural anesthesia in the parturient.

Methods: Sixty healthy women were given epidural anesthesia for labor and delivery. The study was approved by the Institutional Review Board and informed consents were obtained from all patients. After prehydration, group I patients (n=30) received 2% chloroprocaine with 1:300,000 epinephrine and group II patients (n=30) received 2% plain chloroprocaine in a double-blind, randomized fashion. Chloroprocaine used was bisulfite-free. Parameters recorded during the study included duration of analgesia, progress of labor, fetal heart rate parameters and the neonatal outcome as ascertained by Apgar scores, umbilical vein and artery acid base status and the Neurologic and Adaptive Capacity Scores (NACS). Data were analyzed using Student's t-test or chi-square when appropriate. A P value of less than 0.05 was considered statistically significant.

Results: All patients obtained satisfactory analgesia with chloroprocaine with no major adverse experiences. Duration ($\bar{X}$, min±SEM) was significantly longer in group I compared to group II patients (74.2 ±4.4 and 54.6±2.5)respectively ($P<0.001$).

Addition of epinephrine to chloroprocaine did not have any significant effects on duration of first or second stages of labor, mode of delivery or fetal heart rate parameters. Maternal heart rate and the incidence of hypotensive episodes did not differ significantly between the two groups of patients. Apgar scores, neonatal acid base status and the NACS were equally good in the two groups of patients.

Discussion: Results from our study show that the reformulation of 2-chloroprocaine without the bisulfite produces satisfactory anesthesia for labor and delivery. The data also demonstrates that addition of epinephrine to chloroprocaine in small doses significantly prolongs the duration of analgesia and is safe for the mother, fetus and neonate, and does not cause any adverse effects on the progress of labor. The last finding contradicts other reports in which epinephrine added to local anesthetics was shown to prolong labor. The relatively small dose of epinephrine used in our study might have been a factor accounting for the conflicting results. Effects of absorbed epinephrine on uterine blood flow are controversial. In the present study we did not measure uterine blood flow but we did evaluate the effects of the added epinephrine on the fetus and the neonate and found no deleterious effects. More recently, Albright et al found no significant changes in the intervillous blood flow when small doses of epinephrine are added to local anesthetics for lumbar epidural anesthesia in the parturient (3). Further work may be needed to determine whether these results are applicable to high risk patients with impaired uteroplacental blood flow.

References:

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